

Package leaflet: Information for the patient

Deferiprone 500mg film-coated tablets Deferiprone 1000mg film-coated tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.
- Attached to this leaflet you will find a patient/carer reminder card. You should detach, complete, read the card carefully and carry it with you.

What is in this leaflet:

1. What Deferiprone tablets are and what they are used for
2. What you need to know before you take Deferiprone tablets
3. How to take Deferiprone tablets
4. Possible side effects
5. How to store Deferiprone tablets
6. Contents of the pack and other information

1. What Deferiprone tablets are and what they are used for

Deferiprone film-coated tablets (called Deferiprone tablets throughout the rest of this leaflet) contain the active ingredient deferiprone. Deferiprone is an iron chelator, a type of medicine that removes excess iron from the body.

Deferiprone tablets are used to treat iron overload caused by frequent blood transfusions in patients who have a condition called thalassaemia major. This medicine is used when patients cannot take deferoxamine.

2. What you need to know before you take Deferiprone tablets

Do not take Deferiprone tablets:

- if you are allergic to deferiprone or any of the other ingredients of this medicine (listed in section 6);
- if you have a history of repeated episodes of neutropenia (low white blood cell (neutrophil) count);
- if you have a history of agranulocytosis (very low white blood cell (neutrophil) count);
- if you are currently taking medicines known to cause neutropenia or agranulocytosis (see “Using other medicines”);
- if you are pregnant or breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Deferiprone tablets:

- the most serious side effect that may occur while taking deferiprone is a very low white blood cell (neutrophil) count. This condition, known as severe neutropenia or agranulocytosis, has occurred in 1 to 2 out of 100 people who have taken deferiprone in clinical studies. Because white blood cells help to fight infection, a low neutrophil count may place you at risk of developing a serious and potentially life-threatening infection. To monitor for neutropenia, your doctor will ask you to have a blood test (to check your white blood cell count) performed regularly, as frequently as every week, while you are being treated with Deferiprone tablets. Please refer to the patient/carer reminder card attached to this leaflet. **Report immediately to your doctor any symptoms of infection such as fever, sore throat or flu-like symptoms.**
- if your white blood cell count becomes very low, whilst you are taking deferiprone, your doctor might tell you to stop taking this medicine and may ask you to avoid contact with other people to avoid getting an infection. He/she may also ask you to go to hospital.
- if you are HIV positive or if your liver function is severely impaired, your doctor may recommend additional tests.

Your doctor will also ask you to come in for tests to monitor body iron load. In addition, he or she might ask you to undergo liver biopsies.

Your doctor may monitor the levels of zinc in your body, whilst you are taking deferiprone, and you may be asked to take a zinc supplement.

Whilst you are taking Deferiprone tablets, your urine may look discoloured (a reddish/brown colour). This is a common side effect of taking these tablets, but it is not harmful.

Other medicines and Deferiprone tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Do not take medicines known to cause low white blood cell count (neutropenia) with Deferiprone tablets.

Do not take **antacids containing aluminium** at the same time as taking Deferiprone tablets.

Please consult with your doctor or pharmacist before taking **Vitamin C** with Deferiprone tablets.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine.

This medicine could seriously harm your baby.

You must use effective contraception whilst you are taking your medicine. Ask your doctor which method is best for you.

If you become pregnant whilst taking Deferiprone tablets, stop taking your medicine immediately and tell your doctor.

Do not use Deferiprone tablets whilst you are breast-feeding. Please refer to the patient/carer reminder card attached to this leaflet.

3. How to take Deferiprone Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Deferiprone tablets can be taken with or without food; however, you may find it easier to remember to take your medicine if you take it with your meals;
- The 500mg and 1000mg tablets can be divided into equal doses.

Adults

- The recommended dose is based on your body weight.
- Your doctor will decide how much to give you.
- The usual dose is 25mg/kg, three times per day (to give a total daily dose of 75mg/kg).
- The total daily dose should not exceed 100mg/kg.
- Take your first dose in the morning, your second dose midday and your third dose in the evening.

Children

There are limited data available on the safety of deferiprone in children. If the doctor decides that your child needs this medicine, they will determine the most appropriate dose to give.

If you take more Deferiprone tablets than you should

If you take more tablets than your doctor has told you to, contact a doctor or your nearest hospital casualty department immediately and take this medicine with you.

If you forget to take Deferiprone tablets

- Your medicine will be most effective if you do not miss any doses;
- If you do forget to take a dose, take it as soon as you remember unless it is almost time for the next dose;
- **Do not** take double the amount to make up for a forgotten dose;
- **Do not** change your daily dose without first talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most serious side effect of Deferiprone tablets is a very low white blood cell (neutrophil) count. This condition, known as severe neutropenia or agranulocytosis, has occurred in 1 to 2 out of 100 people who have taken deferiprone in clinical studies. A low white blood count can be associated with a serious and potentially life-threatening infection. **Report immediately to your doctor any symptoms of infection such as fever, sore throat or flu-like symptoms.**

Take immediate action if you have the following side effect:

- allergic reactions. Signs of a severe allergic reaction may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**

Other possible side effects:

Very common side effects (may affect more than 1 in 10 people)

- stomach pain
- feeling or being sick
- reddish/brown discoloration of urine (a very common effect which is not harmful)

Common side effects (may affect up to 1 in 10 people)

- low white blood cell count (agranulocytosis and neutropenia)
- headache
- diarrhoea
- increase in liver enzymes
- fatigue
- increase in appetite
- pain or swelling in one or more joints which may disappear as you continue to take your tablets

Not known (frequency cannot be estimated from the available data)

- skin rash or swelling or blisters on the skin (hives)

If you experience nausea and vomiting, it may help to take your medicine with some food. Symptoms, such as feeling sick and diarrhoea, may disappear after a few weeks of taking your medicine.

Effects on the nervous system e.g. shaking, double vision, problems with coordination of movement and uncontrollable muscle movement have been reported in children who have been prescribed more than double the maximum recommended dose of 100mg/kg/day for several years. They recovered from these symptoms after discontinuation of the medicine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Deferiprone tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton and blister or label. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

If you have been prescribed Deferiprone tablets in a plastic bottle, you should use the tablets within 70 days, once the bottle has been opened.

If you have been prescribed Deferiprone tablets in a blister strip, and you have a half tablet, you should push this back into the blister pocket, and store the blister strip in the original carton until it is time for your next dose or for a maximum of 48 hours.

Do not use this medicine if you notice any visible signs of deterioration of the blister pack or the tablets. Return it to your pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Deferiprone tablets contain

- The active ingredient is deferiprone.
- Each Deferiprone 500mg film-coated tablet contains 500mg deferiprone.
- Each Deferiprone 1000mg film-coated tablet contains 1000mg deferiprone.
- The other ingredients are (maize) starch pregelatinised (partially), magnesium stearate, hypromellose, hydroxypropylcellulose, titanium dioxide and macrogol 6000

What Deferiprone tablets look like and contents of the pack

Deferiprone 500mg tablets are white to off-white film-coated tablets with a score line on one side and plain on the other. Tablets can be divided into equal halves.

Deferiprone 500mg tablets may be supplied in blister packs or plastic bottles of 100 tablets.

Deferiprone 1000mg tablets are white to off-white film-coated tablets with a score line on one side and plain on the other. Tablets can be divided into equal halves.

Deferiprone 1000mg tablets may be supplied in blister packs of 50 tablets or plastic bottles of 50 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mercury Pharmaceuticals Ltd

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Manufacturer

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For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

This leaflet was last revised in August 2023.

PATIENT/CARER REMINDER CARD

<p>((Front Cover))</p> <p>Important Safety Reminders for Patients taking Deferiprone tablets</p> <p>Prescribing doctor:</p> <p>Phone No:</p>	<p>((Back Cover))</p> <p>FOR WOMEN OF CHILDBEARING AGE</p> <p>Do not take Deferiprone tablets if you are pregnant or if you are trying to become pregnant. If taken during pregnancy, Deferiprone tablets may seriously harm the unborn baby.</p> <p>You must use effective contraception while you are taking Deferiprone tablets. Ask your doctor which method is best for you. If you become pregnant while taking Deferiprone Tablets, stop taking the medicine immediately and tell the doctor. Do not take Deferiprone tablets if you are breastfeeding.</p>
<p>((Inside 1))</p> <p>MONITORING YOUR WHITE BLOOD CELL COUNT WITH DEFERIPRONE TABLETS</p> <p>There is a small chance that you may develop agranulocytosis (very low white blood cell count) while taking Deferiprone tablets, which may lead to a serious infection. Even though agranulocytosis only affects 1 to 2 out of 100 users, it is important to monitor your blood on a regular basis.</p>	<p>((Inside 2))</p> <p>Make sure you do the following:</p> <ol style="list-style-type: none">1. Have your blood monitored on a weekly basis.2. Contact your doctor immediately if you develop a fever, sore throat or flu-like symptoms.